

**Support for Amendments:**

Claim 11 is amended to characterize the presence of immobilized ligand on the separation matrix, before and after reducing the microbial content. The amendment is supported by the specification at page 8 and the line 31 through page 9, line 6.

Claim 24 is amended to remove the reference to the EP 1997 test protocol. The amendment is supported by the specification at, for example, page 19, lines 9-17.

New claim 25 is supported by the specification at, for example, page 19, lines 9-17.

New claims 26-30 are supported by the specification at page 8, line 31 through page 9, line 6.

No new matter is introduced by this amendment, and entry thereof is requested. Upon entry, claims 11-30 are active in this application.

### **Remarks**

It is unclear whether the outstanding Office Action includes a rejection of claim 24 under 35 U.S.C. §112, second paragraph. To the extent that claim 24 is rejected, is submitted that the rejection has been rendered moot by the amendment to claim 24. Withdrawal of the rejection of claim 24 is requested.

The outstanding Office Action includes a rejection of claims 11, 12, 14-21, 23, and 24 under 35 U.S.C. §102(e) or under 35 U.S.C. §103(a) over U.S. Patent Publication No. US 2003/0100101 to Huth et al. This rejection is traversed.

The presently claimed invention is directed at a method of producing a separation matrix with eliminated or reduced microbially content. The method includes steps of:

providing a microbially contaminated separation matrix in a housing or container, wherein the microbially contaminated separation matrix comprises a polymeric porous material in beaded form, a microfiltration hollow-fiber, or a flat sheet membrane, and wherein separation matrix comprises immobilized ligand;

adding an aqueous antimicrobial preservation composition, which comprises at least one alkyl paraben, to said separation matrix in said housing or container;

allowing said aqueous antimicrobial preservation composition to exert its effect in said housing or container until the number of colony forming units (CFU) per g preservative composition is sufficiently reduced; and

rinsing said aqueous antimicrobial preservation composition from said housing or container to provide the separation matrix with eliminated or reduced microbial content and containing the immobilized ligand.

Huth et al. describe providing a single-use simultaneous cleaning and decontamination (high- or intermediate – level disinfection or sterilization) of a device such as an endoscope. See Huth et al. at paragraph 46. The outstanding Office Action refers to paragraph 18 of Huth et al. See page 5 of the outstanding Office Action. This portion of Huth et al. is in the section entitled “Description of Related Art,” and describes kidney dializers. However, Huth et al. fail to disclose a separation matrix comprising an immobilized ligand, or a process for eliminating or reducing microbial content of a

separation matrix containing immobilized ligand, and in a manner that is sufficiently gentle so that the separation matrix retains the immobilized ligand.

It is submitted that one having ordinary skill in the art would not have received a suggestion from Huth et al. to achieve the presently claimed invention. Accordingly, withdrawal of the rejection over Huth et al is requested.

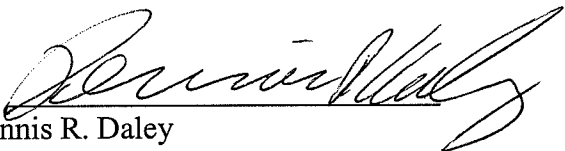
It is believed that this application is in condition for allowance. Early notice to this effect is noticeably solicited.



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Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

By   
Dennis R. Daley  
Reg. No. 34,994  
DRD/mls/np

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